INFORMATION ADVISORY

Subject/Lead Component: Internet posting of results of the legislatively mandated 2001 study "National Evaluation of Private Sector Written Consumer Information for Prescription Drugs" with FDA's response and plan based on this evaluation.

Why This Information Is Critical Now: Posting will occur within a week, and the results and plan may be seen as controversial by some stakeholder groups.

SUMMARY:

- Public Law 104-180 (August 1996) requires the Department to evaluate the usefulness of prescription drug information written and distributed by the private-sector to consumers. If goals set by PL 104-180 are met by the private sector, FDA is prohibited from implementing a program requiring FDA-approval of all written prescription drug information given to patients. If the goals are not met, FDA can take action to regulate these materials.
- Goals for patients receiving useful written prescription information were 75% by 2000 and 95% by 2006.
- "Usefulness" was defined according to eight criteria developed by a stakeholder consensus process facilitated by the Keystone group. These eight criteria were operationalized in a 1999 pilot study and shared with the public, then refined and applied in the 2001 Agency study.
- The results of the 2001 Agency study of the provision of written prescription drug information to consumers indicate that distribution goals are being met (89% of study patients received written information for all four study drugs) but that overall usefulness, based on the consensus-based criteria, ranged from 51-55% (on a scale of 0-100%).
- The 2001 study showed that scientific accuracy of the information provided was very high (>95%), but that important information for patients (on risks and getting the most benefit from the medications) was often incomplete or of poor quality.
- FDA sees progress in meeting the goals of P.L. 104-180 as well as opportunities for improvement, and so would like to defer regulation for now and continue to work with the private-sector to improve performance by 2006.
- Consumer groups are likely to oppose FDA's deferral of regulation or acceptance of less than complete compliance with the consensus-based criteria. Drug companies and pharmacy groups will welcome continued lack of FDA regulation. Medical professional groups are unlikely to take a strong position on either side.

STATUS:

- FDA will publicly announce via talk paper or press release a summary of study findings along with a statement of intent to defer regulatory decision to 2006. The study report itself will be posted on the FDA Internet website as soon as technically possible.

- A meeting of the FDA Center for Drug Evaluation and Research Drug Safety and Risk Management Advisory Committee is planned for July 17, 2002 to discuss means to improve the usefulness of written consumer information. The meeting notice will be timed to occur shortly after the study results are available to the public.

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